

INTEGRATIVE THERAPEUTICS INC. NF Formulas « PhytoPharmica Tyler Encapsulations . Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.282.0467 5 **OPHARMICA** 

825 Challenger Drive, Green Bay, WI 54311-8328 P:-920:469.1313 F: 888.570.6460 (Enzymatic) [P] 9207469 9997 F: 920.469.4418 (Phyto)

## RCDPFDFATED

Wbat **Better** feels like:"

March 14, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Prug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Greens Formula	Natural detoxification support*	Greens Blend: barley grass, alfalfa sprouts, broccoli sprouts, radish sprouts, oat grass, wheat grass, alfalfa juice concentrate European Elder Berry Extract, Vegetable Blend: broccoli flower, cabbage leaf, carrot root, collard greens, tomato fruit, mustard greens, kale leaf, spinach leaf Green Tea Leaf Extract, Seaweed Blend: dulse, blue-green algae, kelp leaf and stem Stevia Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_3/14/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

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What Better feels like."

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March 14, 2005

#### INTEGRATIVE THERAPEUTICS INC."

NF Formulas « PhytoPharmica
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9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 \* F: 503.582.0467

# ENZYMATIC THERAPY & PHYTOPHARMICA'

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Greens Formula	Guar gum extract squble fiber in addition to its ability to the support the retention of healthy cholesterol levels already within normal limits.* In clinical trial, guar gum significantly supported blood glucose levels already within normal range compared with controls.*	Guar gum seed extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Kildlilli

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/14/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,



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9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467 ENZYMATIC THERAPY\*
&
PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

March 14, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Greens Formula	A randomized, double-blind clinical study found that a broccoli and cabbage combination supports healthy cholesterol levels already within normal range after 9 weeks.*	Cabbage leaf

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

FLICILE.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/14/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,



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March 14, 2005

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9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 • F: 503.582.0467

# ENZYMATIC THERAPY & PHYTOPHARMICA\*

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Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

College Park, MD 20740

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PRODUCT	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE
NAME		CLAIM REFERS
Greens	Kale naturally has high levels of carotenoids,	Kale leaf
Formula	lutein and beta-carotene and supports the	
	absorption of magnesium, a crucial mineral for	
	healthy bones.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

	KINCIE.
Ву:	•

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/14/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincercly.

Michael P. Devereux Chief Financial Officer

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March 14, 2005

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
1	Shown in laboratory studies to have immune supportive effects.*	Spinach Leaf

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:		
7	Robert C. Doster	
Title:	Senior Vice President of Scientific	Affairs
D-4	3/14/05	
Date:	3111102	

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Greens Formula	The polyphenols in green tea, specifically EGCG, have been the subject of many scientific studies showing their antioxidant activity. EGCG have been shown to support colon, breast and prostate health.*	Green Tea Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Bv:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date:

3/14/05

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Sincerely



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PRODUCT NAME		INGREDIENT(S) TO WHICH THE CLAIM REFERS
Greens Formula	Green tea has been shown to support the	Green Tea Leaf Extract
	immune system and T-cell formation.*	

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By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/14/05

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Sincerely.



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Greens Formula	Green tea consumption is also associated with cardiovascular support, and research also shows that green tea may regulate mitochondrial functions and have iron chelating properties.*	Green Tea Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:	KIRCHT	
	Robert C. Doster	

Title: Senior Vice President of Scientific Affairs

Date: 3/14/05

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Sincerely,

Michael P. Devereux

Chief Financial Officer



INCORPORATED

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PRODUCT NAME	<u>STATEMENTS</u>	
Greens Formula	Fiber from dulse supports digestive health; the proteins in this form are highly	Dulse
	bioavailable.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICKL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/14/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,



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PRODUCT NAME		INGREDIENT(S) TO WHICH THE CLAIM REFERS
Greens Formula	Supports the immune system and boost natural killer cell activity.*	Blue-green algae

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/14/65

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# PHYTOPHARMICA'

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Language Statement	PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE
	Greens Formula	Supports the thyroid and thyroid hormone	Kelp leaf and stem
		production and cardiovascular health.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/14/05

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Sincerely,

Chief Financial Officer